REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| GLAXO GROUP LIMITED<br><br>Plaintiff,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED<br><br>Defendants. | ) | Civil Action No. 04-171-KAJ<br><br>**CONFIDENTIAL**<br>**FILED UNDER SEAL** |

**TEVA'S BRIEF OPPOSING GLAXO'S BRIEF CONSTRUING THE DISPUTED CLAIM TERMS OF U.S. PATENT NO. 5,068,249**

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Josy W. Ingersoll (# 1088)
Adam W. Poff (# 3990)
Karen E. Keller (# 4489)
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899
Telephone: (302) 571-6600
kkeller@ycst.com

MERCHANT & GOULD P.C.
Mark D. Schuman
Ronald A. Daignault
Jeffer Ali
Jeffrey C. Brown
3200 IDS Center
80 South 8th Street
Minneapolis, MN 55402

*Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*

Dated: July 28, 2006

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

### FEDERAL CASES

**FEDERAL STATUTES**

## I. NATURE AND STAGE OF THE PROCEEDINGS

This patent infringement action was initiated by Glaxo following Teva's submission of an Abbreviated New Drug Application (" ANDA") under 21 U.S.C. § 355(j) to the Food and Drug Administration ("the FDA") for approval of a generic formulation of Glaxo's Zantac® oral solution, a brand-name drug covered by U.S. Patent No. 5,068,249 (the "'249 patent"). Glaxo has conceded that the '249 patent claims do not literally cover Teva's ranitidine oral solution because the claims require the inclusion of ethanol while Teva's formulation does not include ethanol.

Teva's generic formulation is different from the claims of the '249 patent because it includes **Redacted** rather than ethanol, among other differences.

For its part, Teva has admitted that its formulation has all of the elements of the claims of the '249 patent except: 1) "a stabilizing effective amount of;" 2) "ethanol;" 3) "2.5% to 10% weight/volume ethanol;" and 4) "7% to 8% weight/volume ethanol." Teva's Opening Brief in Support of its Claim Construction ("Teva's Opening Brief") was submitted at the same time Glaxo submitted its Opening Claim Construction Brief Construing the Disputed Claim Terms of Glaxo's U.S. Patent No. 5,068,249. This brief is submitted by Teva in opposition to the arguments set forth by Glaxo in its opening brief on claim interpretation.

## II. SUMMARY OF THE ARGUMENT

The parties agree that, in light of Teva's stipulation concerning all other limitations, four terms in dispute are:

1) "ethanol," a term common to all claims of the '249 patent;

2) "stabilizing effective amount," a term found in Claims 1-10 but not in Claims 11 and 12;

3) "2.5 % to 10% weight/volume ethanol," a term found only in Claim 2; and

4) "7% to 8% weight/volume ethanol," found in Claims 3, 11 and 12.

Despite Teva's stipulation, Glaxo also seeks an advisory opinion to construe claim language not at issue: "aqueous formulation for oral administration," found in Claims 1-10, and "aqueous formulation of ranitidine suitable for oral administration," found in Claims 11 and 12.

Glaxo's construction of the term "ethanol" is wrong because it is a semantic effort to align the text of its issued claim with the accused formulation, not an objective effort to define the term in light of the intrinsic record. Not once did the inventor, its counsel, or the Examiner, during nearly five years of prosecution, identify ethanol as an "organic compound," or as "a lower aliphatic hydrocarbon group having two carbon atoms and one - OH group." The extrinsic record cited by Glaxo does not even use these phrases to define ethanol. Those phrases are the product of litigation strategy, solely derived from Glaxo's attorneys and retained expert. Glaxo's construction is inspired solely by its desire to capture Teva's accused product within the scope of its invention, and its proposed definition should be rejected.

Glaxo's construction of the term "stabilizing effective amount" is not a definition at all. It essentially defines "stabilizing effective amount" with a circular definition of an amount that stabilizes, adding only the verb "enhance" to define the effect of ethanol on the formulation. The '249 patent was not granted to reward the use of ethanol to merely "enhance" the stability of ranitidine - it was granted for what Glaxo alleged was a

"surprising," "substantial," and "important" enhancement of ranitidine stability. The Patent Office granted Glaxo's claims only after it showed a statistically significant improvement in shelf life to the Examiner in a declaration submitted by its scientist, Dr. Hempenstall. Moreover, there is no need to redundantly import the "aqueous formulation" language into the remaining claims by means of defining "stabilizing effective amount." Glaxo's construction of "stabilizing effective amount" should be rejected.

Glaxo's construction of "2.5% to 10% weight/volume ethanol" and "7% to 8% weight/volume ethanol" repeats the text of each limitation verbatim, but then adds the clause, "sufficient to enhance the stability of the ranitidine active ingredient in the aqueous formulation for oral administration." Glaxo's construction is redundant, importing two limitations into Claims 2 and 3 that already exist by virtue of the fact that each claim is dependent on Claim 1. Glaxo's construction also impermissibly re-writes Claims 11 and 12 by importing "stabilizing effective amount," into those claims.

Claims 11 and 12 do not, on their face, contain any requirement of a stabilizing effective amount of ethanol. Claim construction is an effort to understand disputed claim limitations existing in the issued patent, not an opportunity for Glaxo to have this Court re-write its claims altogether.

There is no controversy concerning whether Teva's formulation contains an "aqueous formulation for oral administration," and this Court should refrain from providing Glaxo an advisory opinion on that claim language.

## III. RESPONSE TO GLAXO'S STATEMENT OF THE FACTS

Glaxo's statement of facts, especially its essay on the development of the original Zantac® syrup and Glaxo's efforts to gain FDA approval for various measurements of the shelf life of its commercial product is interesting, but largely not relevant to the task before the Court. As explained in more detail below, the Federal Circuit has been very clear that, when construing patent claims, evidence beyond the four corners of the intrinsic record, while sometimes helpful, is less reliable than the patent and its prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (explaining potential sources of extrinsic evidence and advising that although such evidence may be useful to a court, "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."). Glaxo's efforts to use the improvement in shelf life of its commercial product (18-24 months) as a way of defining the improvement in stability provided by the '249 patent is erroneous. The intrinsic evidence, in particular the Declaration by Dr. Hempenstall during the prosecution of the patent, is the evidence that this Court should use and examine. Dr. Hempenstall never cited to an improved shelf life from 18 to 24 months.

The Federal Circuit has explicitly cautioned that ". . . undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Id.* at 1319 (citing *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)). Glaxo's "Technical Background" section almost exclusively cites to expert opinion, an extrinsic source recognized by the *Phillips* court as "generated at the time of

and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* at p. 1318. It is difficult to understand why so much of Glaxo's construction relies upon the extrinsic record, all of which is hidden from public view until developed in the context of litigation. Regardless, this Court, as directed by *Phillips*, should keep such evidence in its appropriate, secondary context.

## IV. ARGUMENT

### A. The Law Of Claim Construction

This Court has before it two briefs stating each party's view of the appropriate standard by which to construe patent claims. Both parties rely primarily upon the *Phillips* decision, which is not surprising. Glaxo's opening brief, however, under the rubric of "relevant background" injects a suspicious amount of extrinsic evidence. Glaxo's construction of "ethanol," a simple and key element of the claimed invention, undeniably finds its only support with Glaxo's expert, Dr. Anderson, who proposes a definition not once contemplated, mentioned, or discussed in the intrinsic record. For this reason, a detailed examination of *Phillips* is warranted, as this recent decision provides a new look at patent claim construction analysis, designed (ultimately) to create more certainty in the analysis.

The principal issue in *Phillips* was to what extent the specification should be relied on and resorted to in claim construction. *Id.* at 1312. In *Phillips*, the Federal Circuit mandated that intrinsic evidence, particularly the claim language, is the cornerstone of claim construction.

The *Phillips* court analyzed "the extent to which [the court] should resort to and rely on a patent's specification in seeking to ascertain the proper scope" of the claims. *Id.*

at 1312. At issue was the meaning of the term "baffle" as used in plaintiff Phillips' patent. *Id.* At the district court level, the parties agreed on the term's broad dictionary definition, but disagreed over the term's ordinary and customary meaning. The district court considered the claims and the specification and held that a "baffle" must "extend inward from the steel shell walls at an oblique or right angle to the wall face." The district court's interpretation did not follow the dictionary definition. Based on this interpretation, the district court granted summary judgment of non-infringement. *Id.*

On appeal, a three-judge panel of the Federal Circuit held that the term's ordinary meaning was that of its dictionary definition, but held that "[t]he ordinary meaning of a term must be considered in view of the intrinsic evidence: the claims, the specification, and the prosecution history." *Phillips v. AWH Corp.*, 363 F.3d 1207, 1213 (Fed. Cir. 2004). The Federal Circuit limited the term's ordinary meaning, as determined from a dictionary, based on the specification: "From the specification[ ] . . . baffles must be oriented at angles other than 90 degrees." *Id.* Thus, the majority sustained the district court's grant of summary judgment of noninfringement, though on different grounds.

Dissenting, Judge Dyk argued that the Federal Circuit's decision limited the claims to the preferred embodiment. *Id.* at 1216 (Dyk, J., dissenting). He argued that the court should have adopted the term's plain meaning from a dictionary, which would have been "something for deflecting, checking, or otherwise regulating flow," and that summary judgment of non-infringement should have been reversed. *Id.* at 1218 (Dyk, J., dissenting).

The Federal Circuit agreed to rehear the case *en banc* "to resolve issues concerning the construction of patent claims." *Phillips v. AWH Corp.*, 376 F.3d 1382

(Fed. Cir. 2004). This *en banc* decision resulted in a tightening of the rules regarding claim construction. The *en banc* decision held that intrinsic evidence should be the primary source of claim interpretation. The words of the claim are to always be given their ordinary customary meaning to one of ordinary skill in the art at the time of the invention. 415 F.3d at 1313. In some situations, this construction would be readily apparent. *Id.* at 1314. In those situations where the ordinary and customary meaning of a claim term is not readily apparent, however, a court should analyze the intrinsic evidence, and not the extrinsic evidence, to understand the meaning of a claim term as understood by persons of ordinary skill in the art. *Id.*

The *Phillips* court began its tutorial on proper claim construction analysis by focusing on intrinsic evidence. Intrinsic evidence was the most important evidence, as necessitated by 35 U.S.C. § 112. The starting point for claim construction must be the specification because § 112, paragraph 1, requires a patentee to describe the invention in "full, clear, concise, and exact terms as to enable" one skilled in the art to make and use the invention. Moreover, paragraph 2 of § 112 requires a patentee to conclude with claims "particularly pointing out and distinctly claiming the subject matter the applicant regards as his invention." Section 112 requires an inventor to describe in the patent the actual invention being patented. There can be no better source to determine the true meaning of a claim than the specification and claims that meet the requirements of § 112.

The Federal Circuit then reiterated that the claims themselves provide "substantial guidance" about the meaning of claim terms. *Id.* at 1314. The context in which the term is used and other claims (both asserted and unasserted) in the patent can provide guidance

on the meaning of the claims. *Id.* Moreover, usage of a term in one claim can help define the meaning of the same term in other claims. *Id.*

Next, the specification was touted as the "single best guide" to understanding not only the meaning of a disputed term, but the scope of the claim. *Id.* at 1315. The Court noted that the importance of the specification derived from 35 U.S.C. §112, requiring that the specification describe the claimed invention in "full, clear, concise, and exact terms." *Id.* at 1316. Claims are to be construed consistently with the specification, regardless of whether this gives a claim term a definition that is different than the meaning it would otherwise possess. *Id.* A court may "rely heavily" on the specification for guidance in claim construction. *Id.* at 1317.

After discussing the importance of the specification, the Federal Circuit also stated that the prosecution history should be consulted, if in evidence. *Id.* The prosecution history is useful to demonstrate how the inventor understood the invention. *Id.* However, because the prosecution history often lacks the clarity of the specification, it is less useful for claim construction. *Id.*

After discussing the proper evidence to determine the meaning of claim terms, the *Phillips* court then discussed the status of extrinsic evidence. The *Phillips* court rejected the line of cases following the opinion set forth in *Texas Digital Sys., Inc. v. Telegenix,* 308 F.3d 1193 (Fed. Cir. 2002), in which the court advocated claim construction methodology that placed heightened reliance on dictionaries (extrinsic evidence). Evidence beyond the four corners of the patent, while sometimes helpful, was less reliable than the patent and its prosecution history. 415 F.3d at 1318. The *Phillips* court recited five reasons why extrinsic evidence was troublesome in claim construction:

(1) extrinsic evidence is not part of the patent and was not created for the purpose of explaining the patent's scope and meaning;

(2) extrinsic evidence may not reflect the understanding of a person of ordinary skill in the art because it may not have been written for such a person;

(3) extrinsic evidence such as expert reports and testimony is prepared at the time of and for the purpose of litigation and may suffer from bias;

(4) there is such a large universe of extrinsic evidence, much of which might be of "marginal relevance;"

(5) use of extrinsic evidence may be used to change the meaning of claims and undermine the public notice function of patents.

*Id.* at 1318-1319.

In the eyes of the Federal Circuit, the *Texas Digital* case "placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources...." *Id.* at 1320. The *Phillips* court disagreed with the suggestion that the specification was only to be consulted after the ordinary meaning was determined from dictionaries or treatises. *Id.* Giving dictionary definitions of claim terms a more prominent role than the specification and prosecution history improperly restricted the role of the specification in claim construction. *Id.* The *Texas Digital* court's methodology of starting with a dictionary if a definition in the specification was expressly present was "inconsistent with our rulings that the specification is 'the single best guide to the meaning of a disputed term.'" *Id.* Moreover, a dictionary definition would improperly divorce the claim terms from the context of the rest of the patent. *Id.* at 1321. Such abstract constructions of claim terms were inconsistent with patent law. Starting with the broad dictionary definition and failing to recognize how the

specification limits the definition will cause overly broad construction of claims and claim terms. *Id.*

Dictionary use was, however, not entirely banned. *Id.* at 1322. The Federal Circuit recognized that "there is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Judges must "attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." *Id.* The Federal Circuit recognized that it can be difficult to determine if the embodiments in the specification are the outer limits of the claim term or are merely exemplary in nature. *Id.* at 1323. However, the Federal Circuit stated that resolving this problem within the context of the patent itself would "capture the scope of the actual invention" most properly. *Id.* at 1324.

Based on the methodology adopted by the Federal Circuit, it rejected defendant AWH's argument that the term "baffles" should be interpreted restrictively and held:

> Although deflecting projectiles is one of the advantages of the baffles of the '798 patent, the patent does not require that the inward extending structures always be capable of performing that function. Accordingly, we conclude that a person of skill in the art would not interpret the disclosure and claims of the '798 patent to mean that a structure extending inward from one of the wall faces is a "baffle" if it is at an acute or obtuse angle, but is not a "baffle" if it is disposed at a right angle.

*Id.* at 1327. Based on its construction, the court remanded the infringement claims to the district court for further proceedings. *Id.* at 1328.

To summarize, the *Phillips* decision marks a departure from the former canons of claim construction that allowed courts to fully consider both intrinsic and extrinsic evidence. In an attempt to create more certainty in claim construction, the Federal Circuit narrowed the scope of relevant materials upon which courts should base their judgments

regarding the proper scope of claim language. To put it concisely, the *Phillips* analysis emphasizes fidelity to the language of the claim allowed by the Patent Office and disclosed to the public:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

*Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

### B. Teva's Response To Glaxo's Construction Of Terms

Teva's support for its construction of the claim terms at issue is set forth in Teva's Opening Brief, and will not be repeated here. Because Teva's constructions align with the inventor's description of the invention and with the prosecution history they should be adopted. The remainder of this brief is focused on why Glaxo's constructions are wrong.

#### 1. "Ethanol" Must Be Construed To Align With The Intrinsic Record, Not Teva's Formulation.

Glaxo's construction finds no support in the intrinsic record, and must be rejected. When the '249 patent issued to the public in 1991, it disclosed and claimed "ethanol" in each of its 12 claims. (Col. 2, line 66 - Col. 4, line 18). Throughout the patent, the term "ethanol" was used 14 separate times. (Exhibit G at M026-029) ('249 patent with all instances of "ethanol" highlighted and numbered). Not once did the inventor believe it necessary to describe ethanol as "a lower aliphatic hydrocarbon," or an "organic compound." During nearly five years of prosecution before the Patent Office, there is not

once any mention by Glaxo, the Examiner, or Dr. Hempenstall, of the term "ethanol" as a "lower aliphatic hydrocarbon," or an "organic compound."

Glaxo's construction, in truth, is designed to read the '249 patent claims on Teva's accused formulation, an exercise prohibited by patent law. The Federal Circuit is explicit that "claims may not be construed with reference to the accused device." *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (*en banc*). Indeed, the Federal Circuit has recently affirmed this rule, stating "a court may not use the accused product or process as a form of extrinsic evidence to supply limitations for patent claim language." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1331 (Fed. Cir. 2006). The *Hillerich* court recognized that this rule does not forbid the court from "any glimpse of the accused product or process," but was clear that courts must not tailor "a claim construction to fit the dimensions of the accused product or process and to reach a preconceived judgment of infringement or noninfringement." *Id.* In other words, the rule "forbids biasing the claim construction process to exclude or include specific features of the accused product or process." *Id.* This is precisely what Glaxo is doing with its proposed definition.

Glaxo's definition surfaced for the first time in this litigation. It is supported only by Dr. Anderson in his first expert report, disclosed on March 16, 2006, more than fourteen years after the '249 patent issued. (Exhibit E at M021, Anderson 3/16/06 Expert Report, ¶ 74). Dr. Anderson proposed that "ethanol" may be defined by its chemical name, but in addition should contain the clause

Redacted

(*Id.* at ¶

72). Dr. Anderson (on behalf of Glaxo) cites to two Redacted to conjure this definition, neither of which actually state that "ethanol" is referred to by those skilled in the art as Redacted

Dr. Anderson alone, in his expert report, suggests this definition, apparently by combining both Redacted Neither of those references, alone, contain the language proposed by Dr. Anderson, however. In the same report, Dr. Anderson also notes that Redacted is

(Id. at ¶ 74). Dr. Anderson has engaged in the practice prohibited by *Hillerich*.

Dr. Anderson's definition suggests, by linguistic semantics alone, that Redacted and ethanol are equivalent compounds. Indeed, one need only substitute, in Dr. Anderson's definition of ethanol, the words Redacted and the reader is left with Dr. Anderson's definition of This semantics game should be seen for what it is -- a transparent effort to construe the claim language as close as semantically possible to the accused formulation, which uses Redacted not ethanol.

Teva's construction, rather than aggregating and combining dictionary definitions (as Dr. Anderson did), distills various dictionary definitions to their common elements. As pointed out in Teva's Opening Brief, common to all dictionary definitions is that ethanol is a chemical with the formula $C_2H_5OH$. This minimalist definition comports with the absence of a definition of ethanol in the specification and prosecution history of the patent.

Teva's construction most closely aligns with the intrinsic record, while Glaxo's relies solely upon extrinsic, biased, and litigation inspired expert opinion. For these reasons, and for the reasons stated in Teva's Opening Brief, this Court should reject Glaxo's construction, and adopt Teva's.

**2. The Claim Term "Stabilizing Effective Amount" Should Be Construed To Define What A Substantial Enhancement In Stability Means.**

Claims 1 - 10 are the only claims in the '249 Patent with the limitation "stabilizing effective amount." The limitation is part of Claims 2-10 by virtue of the fact that each claim is dependent upon Claim 1. 35 U.S.C. § 112, ¶ 4 ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.").

The "stabilizing effective amount" limitation was added during prosecution to Claim 1 by amendment, but not to Claims 11 or 12. (G00139-140) [1] (amending only Claim 1). No matter how this limitation is construed, it is not present in Claims 11 or 12 of the '249 patent and should not be added to Claims 11 and 12 through claim interpretation. If Glaxo had intended the "stabilizing effective amount" limitation to be a part of Claims 11 and 12, it should have amended those claims to include it, just as it had amended other claims to include it.

Glaxo's assertion that "stabilizing effective amount" is a limitation that appears in Claim 11 (and by dependency also in Claim 12) is predicated on a legally unsupportable statement of law. Glaxo relies upon a vague recognition of what it asserts is "case law" supporting the notion that "consistency of claim interpretation" mandates that "stabilizing

effective amount" be read into independent Claim 11, even though the issued patent clearly does not include the limitation. (Glaxo Brf. at pp. 23-24) (citing *Glaxo Wellcome, Inc. v. Impax Labs., Inc.* 356 F.3d 1348, 1356 (Fed. Cir. 2004)).

Glaxo misreads the holding of *Impax Labs*. In *Impax Labs*, the court properly held that where subject matter is relinquished by amendment during prosecution in one claim, the same subject matter is also relinquished for all other claims "containing the same limitation." *Impax Labs,* 356 F.3d at 1356. The *Impax* court also noted that "[c]laims that do not recite the amended term are not subject to an estoppel." *Id.* Here, Claims 11 and 12 do not recite the "stabilizing effective amount" limitation. Glaxo's vague notion of "consistency of claim interpretation" does not apply here.

Glaxo's underlying construction of "stabilizing effective amount" also is not aligned in any way with the '249 patent specification, nor is it consistent with the prosecution history. Indeed, Glaxo's definition is not a definition at all. It is circular. Glaxo defines the limitation "stabilizing effective amount" as any amount "sufficient to enhance the stability of ranitidine." (Glaxo Brf. at pp. 23-24). The specification, however, declares that ranitidine syrups "may be substantially enhanced by the addition of ethanol to the formulation." (Col. 1, lines 40-44) (emphasis added). During prosecution, the Examiner demanded experimental data "to show a definite improvement over" the prior art. (G000200). Glaxo's scientist, Dr. Hempentsall, provided data to that Patent Office and declared that it showed "a significant and surprising enhancement in the stability of ranitidine." (G000209). Only after a "significant and surprising"

[1] File history documents, referenced herein within the range G000111 through G000308, are attached as Exhibits 2 and 3 to the Joint Claim Construction Statement filed on June 30, 2006 (D.I. Nos. 106-107).

improvement in stability was demonstrated to the Patent Office, did Glaxo receive its claims.

Glaxo's expert agrees. Dr. Anderson's testimony on this point was not equivocal. He was asked during his deposition about the '249 patent specification's use of the phrase "substantially enhanced," and the following exchange occurred:

Redacted

(Exhibit H at M031, Anderson Depo. p. 53, ll. 10-18). The bottom line is that Glaxo was not granted a patent for the use of ethanol to simply "enhance" ranitidine stability. The Examiner demanded evidence of a measurable "definite improvement over" the prior art. (G000200). Glaxo responded with data and analysis, allegedly showing a "significant and surprising enhancement in stability of ranitidine." (G000209). Had Glaxo advocated during prosecution (as it does now) that the addition of ethanol merely serves "to enhance the stability of ranitidine," Glaxo would not have received its patent.

Under Glaxo's definition, a formulation with ethanol that can be shown to increase the shelf life of that formulation by even one day would "enhance the stability of" ranitidine. The Examiner, who demanded evidence of "a definite improvement over" the prior art formulation, would not have seen one additional day of shelf life to be "a definite improvement." To the contrary, Glaxo presented data and analysis purporting to prove that ethanol alone, when added to its ranitidine formulation, resulted in an increase

from 13 months to 19 months of shelf life, when measured at 30° C. (G000211). Glaxo's test compared a formulation with ethanol to the same formulation without ethanol in order to support this assertion. (G00209). ("The advantageous effect resulting from the addition of ethanol to an aqueous based ranitidine formulation can readily be determined by comparing the stability of the ranitidine in a formulation according to the present invention and the same formulation but without added ethanol.").

Teva's proposed definition, however, is taken directly from the prosecution history. The specification provides no guidance except to show that the stability of ranitidine solution must be "substantially enhanced." Teva's opening brief shows where in Dr. Hempenstall's declaration each word of Teva's proposed definition finds support. (D.I. No. 101, pp. 13-14). This definition, fully supported by the intrinsic evidence, is the one that should be adopted under *Phillips*.

Glaxo's circular definition of "stabilizing effective amount" ignores the intrinsic record. In contrast, Teva's construction closely follows the methodology employed by Dr. Hempenstall to measure a "significant and surprising enhancement in stability of the ranitidine." (G000209). While Teva proposes a definition that actually articulates what it means to "substantially" enhance ranitidine stability (consistent with the '249 patent specification), Glaxo's construction ignores any aspect of what the enhancement actually is. Glaxo's proposed construction should, therefore, be rejected.

### 3. This Court Should Reject Glaxo's Efforts To Import Redundant Limitations Into The '249 Patent Claims.

Another significant problem with Glaxo's proposed construction of "stabilizing effective amount" is that Glaxo's construction also imports the extraneous clause "contained in an aqueous formulation for oral administration," into its definition of

"stabilizing effective amount." Glaxo attempts to import this extraneous limitation into the term, despite the fact that that language already is in Claims 2-10 by virtue of those claims' dependency on Claim 1.

The Federal Circuit has long been explicit that a patentee may not proffer a claim interpretation "for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a 'nose of wax.'" *Southwall Technologies v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995) (citing *Senmed, Inc. v. Richard-Allan Med. Indus., Inc.*, 888 F.2d 815, 819 n. 8 (Fed. Cir. 1983)). Should Glaxo's construction be adopted, this Court would read an unnecessary redundancy into Claims 1-10. Read literally, under Glaxo's construction, Claim 1 would be molded to twice state that the formulation involved is an aqueous formulation for oral administration, as follows:

> A pharmaceutical composition which is **an aqueous formulation for oral administration** of an effective amount of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation comprising a ~~stabilizing effective amount~~ an amount sufficient to enhance the stability of the ranitidine active ingredient contained in **an aqueous formulation for oral administration** of ethanol and said composition having a pH in the range of 6.5-7.5.

(Col. 2, line 67 - Col. 3, line 4) (emphasis (bold), Glaxo's proposed change (underline) added, and original claim language deleted (stricken out)). The same redundancy would then be incorporated into each of the claims dependent on Claim 1, Claims 2-10. Further, should "stabilizing effective amount" also be read into Claim 11, the same redundancy would be read into Claims 11-12. Such a liberal claim revision is explicitly prohibited by law. *Southwall Technologies*, 54 F.3d at 1578.

Moreover, this construction improperly imports extraneous and unnecessary limitations into the claims. As stated in Teva's Opening Brief, district courts are consistently cautioned by the Federal Circuit to be careful not to import undue limitations into the definitions of claim terms when they are not necessary. *See Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed Cir. 1998) ("If we need not rely on a limitation to interpret what the patentee meant by a particular term or phrase in a claim, that limitation is 'extraneous' and cannot constrain the claim.") (citations omitted); *see also Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 950 (Fed. Cir. 1993) ("It is improper for a court to add 'extraneous' limitations to a claim, that is, limitations added wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.") (quoting *Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988)).

**4. This Court Should Reject Glaxo's Efforts To Import Extraneous Limitations Into Claims 2 And 3 Of The '249 Patent In The Interpretation Of The Phrases "2.5% To 10% Weight/Volume" And "7% to 8% Weight/Volume."**

Glaxo's back-up scheme for importing the "stabilizing effective amount" limitation into every claim of the '249 patent begins with a spurious construction of "2.5% to 10% weight/volume," and "7% to 8% weight/volume" as recited in Claims 2 and 3 respectively. Glaxo's construction repeats each volume-based limitation verbatim, but adds its construction of "stabilizing effective amount" to both phrases. Glaxo needs to import this limitation into Claims 2 and 3 because this definition for Claim 3 is critical to Glaxo's effort to read "stabilizing effective amount" into Claim 11.

However, Claims 2 and 3 already have the "stabilizing effective amount" limitation (no matter how that clause is construed) by virtue of their respective

dependency on Claim 1. Glaxo's construction would read yet another redundancy into Claims 2 and 3 that is not necessary. Both claims, by operation of law, have all of the limitations of Claim 1, with the further restriction on each formulation requiring differing specific amounts of ethanol. There is no need to repeat the "stabilizing effective amount" limitation in the text of Claims 2 or 3. That limitation already is present, and has nothing to do with the specific volume limitations of ethanol.

To the contrary, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004). As applied here, the specific volumetric limitations stated in Claims 2 and 3 are presumed to be absent from Claim 1, not equated to the "amount" limitation stated in Claim 1, as Glaxo suggests. Indeed, it is reasonable to conclude that Glaxo meant to maintain a difference between Claim 1 and each of the other claims with numerical ranges when it had the opportunity to add the "stabilizing effective amount" language to the numerical range claims, such as Claims 11 and 12, but did not do so. *See Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295 (Fed. Cir. 1999) ("There is presumed to be a difference in meaning and scope when different words and phrases are used in separate claims.") (citing *Tandon Corp. v. ITC*, 831 F.2d 1017, 1023 (Fed. Cir. 1987). Put another way, Glaxo did not "functionally define" the numerical limitations on the amount of ethanol in any manner, even though it could have.

Glaxo argues that its construction of Claims 2 and 3 is consistent with the "legal doctrine that dependent claims incorporate all of the limitations of the independent claim from which they depend." (Glaxo Brf. at p. 31) (citing 35 U.S.C. § 112 para. 4 and *In re*

*Beaver*, 893 F.2d 329, 330 (Fed Cir. 1989)). Glaxo is correct that such a legal doctrine exists, but Glaxo's claim construction actually contradicts the doctrine. The fact that dependent claims incorporate all of the limitations of the independent claim from which they depend means that Glaxo's construction would read "stabilizing effective amount" into Claims 2 and 3 twice. Such redundancy is nothing but an effort by Glaxo to re-write its claims, and must be rejected. *Southwall Tech.*, 54 F.3d at 1578.

**5. Glaxo's Construction Of Claim 11 Is Wrong.**

The true motivation behind Glaxo's proposed interpretation of Claims 2 and 3 is that equating "7% to 8% weight/volume ethanol," as recited in Claim 3, with a "stabilizing effective amount," allows Glaxo to import the same limitation into Claim 11. In general, it is true that the same claim limitation in different claims should be construed consistently. *Phillips*, 415 F.3d at 1314 (stating that "claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.") (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001); and *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1159 (Fed. Cir. 1997)). Thus, if Glaxo succeeds in equating the "7% to 8% weight/volume" limitation of Claim 3 with a "stabilizing effective amount," then Glaxo argues that "7% to 8% weight/volume" as it appears in Claim 11 should be similarly construed. Glaxo's argument, however, fails on two grounds.

First, as established above, there is no legal basis for importing the limitation "stabilizing effective amount" into Claim 2 or Claim 3, because that limitation already is present in those claims due to their respective dependency on Claim 1. Second, Claim 11, as considered and issued by the Patent Office, simply does not include the "stabilizing

effective amount" limitation. Glaxo's construction would effectively re-write Claim 11 and Claim 12 to import a limitation that they do not have. Such a revision of issued claim terms is prohibited. *Southwall Tech.*, 54 F.3d at 1578.

Moreover, Glaxo could have amended Claim 11 to include the "stabilizing effective amount" limitation, but it did not. Glaxo's failure to amend Claim 11 to include this limitation cannot be cured before this Court. The public and Teva have relied upon the text of issued Claims 11 and 12 since 1991, and they may not be amended now. *Phillips,* 415 F.3d at 1312. ("Because the patentee is required to 'define precisely what his invention is,' the Court explained, it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'"(citing *White v. Dunbar*, 119 U.S. 47, 52 (1886)).

**6. This Court Cannot Issue An Advisory Opinion To Construe Limitations That Teva Admits.**

Teva explained, in its opening claim construction brief, that courts need not construe claim limitations that a defendant concedes are met by the accused process. (D.I. No. 157 at pp. 18-19). Teva has admitted its formulation is an aqueous formulation for oral administration, so this Court need not construe this limitation. *U.S. Surgical Co. v. Ethicon*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

## V. CONCLUSION

For the reasons stated above, Teva respectfully urges the Court to adopt its proposed constructions of the disputed claim terms presented for construction.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll (# 1088)
Karen E. Keller (# 4489)
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899
Telephone: (302) 571-6600
kkeller@ycst.com

MERCHANT & GOULD P.C.
Mark D. Schuman
Ronald A. Daignault
Jeffer Ali
Jeffrey C. Brown
3200 IDS Center
80 South 8th Street
Minneapolis, MN 55402
Telephone 612-332-5300

*Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*

Dated: July 28, 2006

**CERTIFICATE OF SERVICE**

I, Karen E. Keller, Esquire, hereby certify that on July 28, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

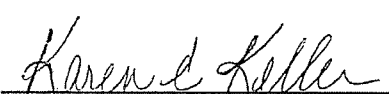
Francis DiGiovanni, Esquire
Connolly Bove Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801

I further certify that on June 30, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

**BY E-MAIL AND FEDEX**

Brian P. Murphy, Esquire
Thomas Puppa, Esquire
Morgan Lewis & Bockius, LLP
101 Park Avenue
New York, NY 10178-0060

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Karen E. Keller (No. 4489)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
kkeller@ycst.com

*Attorneys for Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*

**CERTIFICATE OF SERVICE**

I, Karen E. Keller, Esquire, hereby certify that on August 4, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Francis DiGiovanni, Esquire
Connolly Bove Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801

I further certify that on June 30, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

**BY E-MAIL AND FEDEX**

Brian P. Murphy, Esquire
Thomas Puppa, Esquire
Morgan Lewis & Bockius, LLP
101 Park Avenue
New York, NY 10178-0060

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Karen E. Keller (No. 4489)

Karen E. Keller (No. 4489)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
kkeller@ycst.com

*Attorneys for Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*